



CLIAC Work Group Report

Cytology Proficiency Testing

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Work Group Charge

Openly discuss issues, consider comments and develop potential framework and options for regulatory revisions that will be reported to CLIAC for developing recommendations to HHS for assisting in the development of a proposed rule.



Work Group Considerations

--Cytology proficiency testing issues identified in
organizational and other comments

Individual vs. Laboratory

New technology

Frequency of testing

Number of challenges

Categories of challenges

Number of Challenges per Category

Grading Scheme

Validation

Test site

Retesting

Confidentiality



Individual vs. Laboratory Work Group Comment

- Encourage, but not mandate educational programs for the laboratory
- Lack of participation in a laboratory program should be a flag to the inspectors



Individual vs. Laboratory Regulatory Options

- No change unless Congress changes the Law
 - *Use the preamble to encourage laboratories to participate in educational laboratory programs in addition to individual proficiency testing*
 - *Use guidelines to state that lack of participation in a laboratory program should be a flag to inspectors*



New Technology

Work Group Comments

- Allow digital images and/or digitized slides that test locator and interpretive skills
- Encourage vendors of new technology to provide assistance incorporating technology within PT programs
- Laboratories should use proficiency testing options that most closely reflect actual practice
- Allow a transition phase when the individual can request retesting with glass slides



New Technology Regulatory Options

- Change current language of “slides” to “challenges” to allow for the use of virtual slides
- Define a challenge as a case equivalent – glass slide, virtual slide, or other approved media
- Add requirement for a transition phase for all new technology, when the individual can request retesting with glass



New Technology Regulatory Options, continued

- *Use flexible language that allows programs to adapt new technology to reflect actual practice*
- *Encourage developing tests that include new technology to evaluate testing with a ThinPrep Imaging System or Location Guided Screening*



Frequency of Testing Work Group Comments

- Group was split on whether the test should be given every 2 years, 3 years or 3+ years



Frequency of Testing Regulatory Options

- Reduce the frequency of testing
 - Options:
 - 2-year test cycle
 - 3-year test cycle
 - >3-year test cycle

Decision needed



Number of Challenges Work Group Comment

- 20 challenges (supported by the majority) if testing is less frequent than annual
- 10 challenges



Number of Challenges Regulatory Options

- Change the language to include 20 challenges for initial test and retest with four hours allowed for each test
- Leave language of 10 challenges

Decision needed



Categories of Challenges

Work Group Comments

- Leave the four categories
 - Unsatisfactory
 - Negative
 - LSIL
 - HSIL (includes cancer)



Categories of Challenges Regulatory Options

- No change in the four categories



Number of Challenges/Category Work Group Comment

- If the test is 10 challenges – should not require inclusion of one from each of the four categories to prevent “gaming”
 - Each test include at least 1 HSIL and 1 Negative
 - 50% of test include 1 LSIL and 1 Unsatisfactory
- If the test is 20 challenges – include at least one from each of the four categories



Number of Challenges/Category Regulatory Options

- No change if 20 challenges per test
- Change language if 10 challenges are kept in place to include
 - At least 1 HSIL and 1 Negative in all test sets
 - At least 1 LSIL and 1 Unsatisfactory in 50% of the test sets

Decision needed

CLIA Grading Scheme

Correct Response	Pathologist (Technical Supervisor) 10-Slide Test			
	Examinee Response			
	A – UNSAT	B - NEGATIVE	C – LSIL	D – HSIL
A – UNSAT	10	0	0	0
B – NEGATIVE	5	10	0	0
C – LSIL	5	0	10	5
D – HSIL	0	-5	5	10

Correct Response	Cytotechnologist 10-Slide Test			
	Examinee Response			
	A – UNSAT	B- NEGATIVE	C – LSIL	D – HSIL
A – UNSAT	10	0	5	5
B – NEGATIVE	5	10	5	5
C – LSIL	5	0	10	10
D – HSIL	0	-5	10	10 ¹⁸



Grading Scheme

Work Group Comments

- Remove -5 automatic failure on the basis of a single slide (or case equivalent)
- Point value for a correct response LSIL slide called unsatisfactory should be “0”
- Unified scoring system
 - No agreement of using same scoring system for pathologists and cytotechnologist
 - No agreement of whether there should be a distinction of point value for LSIL/HSIL for pathologist



Grading Scheme Work Group Comments

- Several grading schemes were considered and tested using Maryland data

Details of the grading scheme analysis will be presented by Devery Howerton



Grading Scheme

Regulatory Options

- Change scoring grid to remove automatic failure (-5 points for calling a HSIL slide negative)
- Change scoring grid from "5" to "0" points when a correct response of LSIL is called unsatisfactory
- If another grading scheme model is selected, change language

Decision needed



Validation

Work Group Comments

- Require field validation of each challenge that is continuously updated through out testing
- Require biopsy confirmation of HSIL slides, but not LSIL slides
- Require validation procedures to be disclosed to by the vendor



Validation

Regulatory Options

- Add requirement to include field validation of challenges in addition to referencing by 3 pathologist
- Add requirement for PT providers to disclose what validation process is used
- Delete language for biopsy confirmation of LSIL (leave HSIL biopsy confirmation)



Testing Site Work Group Comment

- On-site for initial test
- Off-site testing centers or professional meetings as an option for a missed test or retest
- Allow laboratories to designate a proctor



Testing Site Regulatory Options

- *Law states on-site testing, however the PT provider can determine alternate test sites for retesting—the preamble could be used to encourage more options for test sites*
- *The PT provider determines the proctor requirements*



Retesting/Remediation Work Group Comment

- Appeal process should be stated
- State as “Individuals who score <90% must....(eliminate the use of the word fail)
- Must pass one program before switching to another program



Retesting/Remediation Regulatory Options

- Add requirement for PT providers to disclose the appeal process in writing
- Change language to state individuals who scores <90% must...(as opposed to "who fail")
- *Individuals are currently required to pass one testing cycle before switching PT providers*



Confidentiality

Work Group Comments

- Reaffirm that individually identifiable results are not made public except under special circumstances (in contrast to laboratory PT results)



Confidentiality Regulatory Options

- CMS Informational Supplement –
www.cms.hhs.gov/CLIA/downloads/Informational_Supplement.pdf
 - 2005-2006 testing cycle educational – names will not be collected by CMS unless there is a survey or complaint
 - End of 2006 CMS will reassess whether individual names will be maintained
 - Agency records maintained in the Cytology Personnel Record System (CYPERS)– published in the Federal Register (70 FR 2637)



Options for Regulatory Revisions Summary

- Change current language of “slides” to “challenges” to allow for the use of virtual slides
- Define a challenge as a case equivalent – glass slides, virtual slide, or other approved media
- Add a requirement for a transition phase for all new technology when the individual can request retesting with glass slides



Options for Regulatory Revisions Summary

- Reduce the frequency of testing – decision of time frame between testing cycles
- Change the language to include 20 challenges for all initial test and all retests with four hours allowed for testing



Options for Regulatory Revisions

Summary

- Changes in scoring grid – decision on unified scoring and loss of points for LSIL/HSIL distinction
- Add a requirement for field validation that is disclosed by PT provider
- Delete requirement for biopsy confirmation of LSIL



Options for Regulatory Revisions

Summary

- Add requirement for PT providers to disclose the appeal process in writing
- Change language to state individuals who scores <90% must...(as opposed to “who fail”)